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| APPLICATION NO. | FIL | LING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO |
|-----------------------|---------|---------------|--------------------------|---------------------|-----------------|
| 10/618,848 07/15/2003 | | 7/15/2003 | Frank Bonadio | 08203.0003-01000 | 4339 |
| 22852 | 7590 | 06/24/2005 | | EXAMINER | |
| | N, HEND | ERSON, FARABO | FLANAGAN, BEVERLY MEINDL | | |
| LLP 901 NEW Y | ORK AVE | NUE, NW | ART UNIT | PAPER NUMBER | |
| WASHING | ON, DC | 20001-4413 | 3739 | | |

DATE MAILED: 06/24/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | Application No. | Applicant(s) | | | | | |
|---|---|---|--|--|--|--|--|--|
| | | 10/618,848 | BONADIO ET AL. | | | | | |
| | Office Action Summary | Examiner | Art Unit | | | | | |
| | | Beverly M. Flanagan | 3739 | | | | | |
| | The MAILING DATE of this communication appears on the cover sheet with the correspondence address Period for Reply | | | | | | | |
| A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION. - Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication. - If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely. - If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication. - Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b). | | | | | | | | |
| Status | | | | | | | | |
| 1) | Responsive to communication(s) filed on | · | | | | | | |
| 2a) <u></u> □ | This action is FINAL . 2b)⊠ This | s action is non-final. | | | | | | |
| | Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under <i>Ex parte Quayle</i> , 1935 C.D. 11, 453 O.G. 213. | | | | | | | |
| Disposition | Disposition of Claims | | | | | | | |
| 5) [| Claim(s) <u>1-17</u> is/are pending in the application 4a) Of the above claim(s) is/are withdra Claim(s) is/are allowed. Claim(s) <u>1-17</u> is/are rejected. Claim(s) is/are objected to. Claim(s) are subject to restriction and/o | wn from consideration. | | | | | | |
| Application | on Papers | | | | | | | |
| 9)[] 1 | The specification is objected to by the Examine | er. | | | | | | |
| 10) The drawing(s) filed on is/are: a) ☐ accepted or b) ☐ objected to by the Examiner. | | | | | | | | |
| Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a). | | | | | | | | |
| Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d). 11) The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152. | | | | | | | | |
| ,— | , | Administration the discount of the | 7.00.00.00.00.00.00.00.00.00.00.00.00.00 | | | | | |
| Priority under 35 U.S.C. § 119 12) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f). a) All b) Some * c) None of: 1. Certified copies of the priority documents have been received. 2. Certified copies of the priority documents have been received in Application No. 3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)). * See the attached detailed Office action for a list of the certified copies not received. | | | | | | | | |
| Attachment | (5) | | PRIMARY EXAMINER | | | | | |
| 1) Notice of References Cited (PTO-892) 4) Interview Summary (PTO-413) | | | | | | | | |
| 3) 🔲 Inform | e of Draftsperson's Patent Drawing Review (PTO-948) nation Disclosure Statement(s) (PTO-1449 or PTO/SB/08) No(s)/Mail Date | Paper No(s)/Mail Da 5) Notice of Informal P 6) Other: | ate atent Application (PTO-152) | | | | | |

Art Unit: 3739

DETAILED ACTION

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7, 9, 10 and 17 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 7, 9 and 10, the phrase "or each eversion limiting means" is indefinite and lacks proper antecedent basis in independent claim 1. Claim 1 recites "at least one eversion limiting means". In claim 17, the phrase "sealing means" lacks proper antecedent basis in independent claim 1. For examination purposes, it was assumed that applicant intended to make claim 17 dependent upon claim 15.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-17 are rejected under the judicially created doctrine of double patenting over claims 1-25 of U. S. Patent No. 6,623,426 since the claims, if allowed, would improperly extend the "right to exclude" already granted in the patent.

The subject matter claimed in the instant application is fully disclosed in the patent and is covered by the patent since the patent and the application are claiming common subject matter, as follows: A surgical access device comprised of a sleeve with inner and outer wall sections defining a lumen for receiving an object, an inflation space between the two wall sections, a ring comprising an eversion limiting means and eversion of the sleeves resulting in the inner sleeve section rolling outwardly and the outer sleeve section correspondingly rolled inwardly.

Furthermore, there is no apparent reason why applicant was prevented from presenting claims corresponding to those of the instant application during prosecution of the application which matured into a patent. See *In re Schneller*, 397 F.2d 350, 158 USPQ 210 (CCPA 1968). See also MPEP § 804.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-5, 7-10, 15 and 17 are rejected under 35 U.S.C. 102(b) as being anticipated by Mollenauer et al. (U.S. Patent No. 5,634,937).

Application/Control Number: 10/618,848 Page 4

Art Unit: 3739

In regard to claims 1-5, 7-10, 15 and 17, Mollenauer et al. teach a medical sealing device 10 for engaging an incision in a patient, comprising a pliable sleeve 45 having an inflation port 51 and an incision engageable wall section 50 a moveable wall section 49, an inflation space between the wall section 50 and wall section 49 and a longitudinal axis, as well as a flexible elastic ring 48 for assisting in maintaining the sleeve against a wall of the incision where the moveable wall section 49 moves relative to the incision engageable wall section 50 and forms a central lumen 47 extending along the longitudinal axis and inflation of the inflatable space urges the central lumen into a sealed position (see col. 10, lines 26-45). Figure 16 and 17 show that the moveable wall section 49 assists in the sealing of an object extended through the lumen 47 and is moveable upon engagement and axial movement of the object within the lumen 47 by eversion so that a part of an inner portion of the sleeve moves to become a part of an outer portion of the sleeve and a section of the outer portion of the sleeve moves to become a section of the inner portion of the sleeve (note that the sleeve is inherently evertable, because the tube 48 is not mounted to the balloon; see also col. 9, lines 62-65).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over Mollenauer et al. (U.S. Patent No. 5,634,937) in view of Ou (U.S. Patent No. 5,636,645).

In regard to claim 16, Mollenauer et al. are silent as to a glove mounted on the sleeve 45 to receive a surgeon's hand. However, Ou discloses a similar sealing device comprised of a surgical glove 30 with a hand portion 32 attached to an inflatable cuff 38 (see Figures 3 and 6). Ou thus demonstrates that providing an inflatable sealing device with an attached surgical glove it well known in the art. Accordingly, it would have been obvious for one of ordinary skill in the art at the time the invention was made to provide the sleeve 45 of Mollenauer et al. with the surgical glove 30 disclosed by Ou.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Beverly M. Flanagan whose telephone number is (571) 272-4766. The examiner can normally be reached on Mondays, Tuesdays and Thursdays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda C.M. Dvorak can be reached on (571) 272-4764. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Application/Control Number: 10/618,848

Art Unit: 3739

Page 6

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Beverly M. Flanagar

Aft Unit 3739
